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FEB 1 2 2010

510(k) Summary - SimpliSeal

1. Contact Person:

Clark D. vonAhsen

Associate, Regulatory Affairs

Discus Dental, LLC 8550 Higuera Street Culver City, CA 90232 310.845.8216 – phone 310.845.8647 – fax clarky@discusdental.com

Date of Summary Preparation:

May 28, 2009

2. Name of Medical Device

Proprietary Name:

SimpliSeal

Common/Usual Name:

Root Canal Sealer

Classification Name:

Resin, Root Canal Filling (KIF)

3. Substantial Equivalence Determination:

Discus Dental, LLC believes that SimpliSeal is substantially equivalent to the following commercially marketed products:

Predicate Device	<u>Company</u>	<u>510(k) No.</u>
Adseal	Meta BioMed Co., LTD	K042769
AH-Plus	Dentsply Intl.	K960548

4. Description of Medical Device:

SimpliSeal is a root canal sealer delivered in a dual-barrel syringe. This epoxy based resin sealer is easy to use with gutta-percha points and can also be used with established and more recent root canal sealing techniques. SimpliSeal provides permanent obturation of root canals when combined with obturation points.

5. Intended Use:

SimpliSeal is a root canal sealer for the permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).

SimpliSeal is intended for use by qualified healthcare personnel trained in its use.

6. Discus Dental, LLC believes that SimpliSeal is substantially equivalent to the following commercially marketed products:

	Discus Dental	Meta BioMed Co., LTD	Dentsply Intl.
	SimpliSeal	Adseal	AH-Plus
Labeling	Permanent root canal sealer	Permanent root canal sealer	Permanent root canal sealer
Intended Use	SimpliSeal is a root canal sealer for the permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points). Intended for use by qualified healthcare personnel trained in its use.	For permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta-percha points). Intended for use by qualified healthcare personnel trained in its use. ISO 6876 fluidity,	AH PLUS Root Canal Sealer is used for permanent sealing of root canals following established endodontic procedures. Intended for use by qualified healthcare personnel trained in its use. ISO 6876 fluidity,
Similar Physical Properties	ISO 6876 fluidity, working time, film thickness, radiopacity, solubility & disintegration	working time, film thickness, radiopacity, solubility & disintegration	working time, film thickness, radiopacity, solubility & disintegration
Design, Construction, Components	Premixed, two part paste, packaged in tow component plastic syringe ready to be dispensed and mixed.	Premixed, two part paste, packaged in tow component plastic syringe ready to be dispensed and mixed.	Premixed, two part paste, packaged in tow component plastic syringe ready to be dispensed and mixed.

The following physical tests have been completed on SimpliSeal:

Setting time – per ISO 6876
Flow – per ISO 6876
Film thickness – per ISO 6876
Solubility – per ISO 6876
Dimensional change following setting – per ISO 6876

. The following biocompatibility tests have been completed on SimpliSeal:

Cytotoxicity – ISO 10993-5 Acute Systemic Toxicity (oral) – ISO 10993-11 Irritation – ISO 10993-10 Sensitivity – ISO 10993-10 Genotoxicity – ISO 10993-3

All testing is within specification and the device performs as designed. The results demonstrate that the device is safe, effective and performs as well as or better than products that are already legally marketed.

END OF 510(k) SUMMARY



Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

FEB 1 2 2010

Mr. Clark D. Von Ashsen Associate, Regulatory Affairs Discus Dental, L.L.C. 8550 Higuera Street Culver City, California 90232

Re: K093208

Trade/Device Name: SimpliSeal

Regulation Number: 21 CFR 872.3820 Regulation Name: Root Canal Filling Resin

Regulatory Class: II Product Code: KIF Dated: January 21, 2010 Received: January 22, 2010

Dear Mr. Von Ashen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

E. Indications for Use Statement

510(k) Number (if known): <u>46932</u>08

SimpliSeal

Device Name:

Indications for Use:

Simplified is intended for use by qualified heal	thcare personnel trained in its use.			
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	ver-The-Counter Use 21 CFR 801 Subpart C)			
(PLEASE DO NOT WRITE BELOW THIS LINE-CO OF NEEDED)	ONTINUE ON ANOTHER PAGE			
Concurrence of CDRH, Office of Device Evaluation (ODE)				
RSBetz Das for Dr. K. P. Muly (Division Sign-Off)	•			
Division of Anesthesiology, General Hospital Infection Control, Dental Devices				
510(k) Number: <u>K093208</u>	Page <u>l</u> of <u></u>			
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